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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/425,501	10/22/99	MARK R	GNN-055

000959
LAHIVE & COCKFIELD
28 STATE STREET
BOSTON MA 02109

HM22/0109

EXAMINER	
WILSON, M	
ART UNIT	PAPER NUMBER
1633	4

DATE MAILED: 01/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/425,501	MARK ET AL.	
	Examiner	Art Unit	
	Michael Wilson	1633	

-- The MAILING DATE of this communication app ars on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-4, 14 and 15, drawn to nucleic acids, a vector, and a neural cell line which express a heterologous Pablo polypeptide classified in class 536, subclass 23.1.

   II. Claims 5-11 and 21, drawn to proteins, chimeric proteins, and a method of identifying a compound using proteins, classified in class 530, subclass 350 and others.

   III. Claim 13, drawn to antisense, classified in class 536, subclass 24.5.

   IV. Claim 16, drawn to a non-human transgenic animal, classified in class 800, subclass 13.

   V. Claims 17 and 18, drawn to a method of modulating apoptosis, classified in various classes and subclasses.

   VI. Claim 19, drawn to a method of treatment, classified in various classes and subclasses.

   VII. Claim 20, drawn to a method of identifying a compound using cells, classified in class 435, subclass 325.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct because the nucleic acids can be used to make transgenic animals while the proteins can be used to isolate antibodies. The protocols and reagents for DNA and proteins are materially distinct and separate. The DNA does not require the protein and the protein does not require the DNA.

Groups I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different modes of operation, different functions and different effects. The DNA of group I operates by binding polymerase and producing protein, the function and effect is to encode protein. The antisense of Group III operates by binding to sense strand DNA and functions to affect the function of the sense strand.

Groups I and IV are unrelated because the DNA can be used as a probe while the transgenics can be used as *in vivo* models. The protocols and reagents required to work with DNA as a probe are materially distinct and separate than those required to make transgenics. The DNA does not require the transgenics.

Groups I and V are patentably distinct because the DNA can be used as a probe while the method of modulating apoptosis can be used to alter a cell. The protocols and reagents required for using DNA are materially distinct and separate than those required for modulating apoptosis. The DNA does not require the method and the method does not require the DNA.

Groups I and VI are patentably distinct because the DNA can be used as a probe while the method of treatment can be used to treat disease. The protocols and reagents required for using DNA are materially distinct and separate than those required treat disease. The DNA does not require the method and the method does not require the DNA.

Groups I and VII are patentably distinct because the DNA can be used as a probe while the method can be used to identify compounds of interest. The protocols and reagents required for using DNA are materially distinct and separate than those required for identifying compounds of interest. The DNA does not require the method and the method does not require the DNA.

Groups II and III are patentably distinct because the proteins can be used to isolate antibodies while the antisense can be used to alter the function of DNA. The protocols and reagents for proteins and antisense are materially distinct and separate. The antisense does not require the protein and the protein does not require the antisense.

Groups II and IV are unrelated because the proteins can be used to isolate antibodies while the transgenics can be used as *in vivo* models. The protocols and reagents required to work with protein are materially distinct and separate than those required to make transgenics. The protein does not require the transgenics and the transgenics do not require the protein.

Groups II and V are patentably distinct because the proteins can be used to isolate antibodies while the method of modulating apoptosis can be used to alter a cell. The protocols and reagents required for proteins are materially distinct and separate than those required for

modulating apoptosis. The protein does not require the method and the method does not require the protein.

Groups II and VI are patentably distinct because the proteins can be used to isolate antibodies while the method of treatment can be used to treat disease. The protocols and reagents required for using proteins are materially distinct and separate than those required treat disease. The protein does not require the method and the method does not require the protein.

Groups II and VII are patentably distinct because (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the groups are patentably distinct because the method of identifying compounds of interest can be practiced with proteins or with cells and because the protein can be used to identify compounds of interest or to isolate antibodies.

Groups III and IV are unrelated because antisense can be used to alter the function of DNA while the transgenics can be used as *in vivo* models. The protocols and reagents required for antisense are materially distinct and separate than those required to make transgenics. The antisense does not require the transgenics and the transgenics do not require the antisense.

Groups III and V are patentably distinct because antisense can be used to alter the function of DNA while the method of modulating apoptosis can be used to alter a cell. The protocols and reagents required for antisense are materially distinct and separate than those

required for modulating apoptosis. The antisense does not require the method and the method does not require the antisense.

Groups III and VI are patentably distinct because antisense can be used to alter the function of DNA while the method of treatment can be used to treat disease. The method encompasses treatment using numerous other compositions including proteins, DNA encoding protein and drugs. The protocols and reagents required for using antisense are materially distinct and separate than those required treat disease using compounds or proteins. The antisense does not require the method and the method does not necessarily require the antisense.

Groups III and VII are patentably distinct because antisense can be used to alter the function of DNA while the method can be used to identify compounds of interest. The protocols and reagents required for using antisense are materially distinct and separate than those required for identifying compounds of interest. The antisense does not require the method and the method does not require the antisense.

Groups IV and V are patentably distinct because transgenics can be used as *in vivo* models while the method of modulating apoptosis can be used to alter a cell. The protocols and reagents required for transgenics are materially distinct and separate than those required for modulating apoptosis. The transgenics do not require the method and the method does not require the transgenics.

Groups IV and VI are patentably distinct because transgenics can be used as *in vivo* models while the method of treatment can be used to treat disease. The protocols and reagents

required for transgenics are materially distinct and separate than those required treat disease. The transgenics do not require the method and the method does not require the transgenics.

Groups IV and VII are patentably distinct because transgenics can be used as *in vivo* models while the method can be used to identify compounds of interest. The protocols and reagents required for transgenics are materially distinct and separate than those required for identifying compounds of interest. The transgenics do not require the method and the method does not require the transgenics.

Groups V and VI are patentably distinct because the method of modulating apoptosis can be used to alter a cell *in vitro* while the method of treatment can be used to treat disease. The protocols and reagents required for modulating apoptosis are materially distinct and separate than those required treat disease. The method of modulating apoptosis does not require the method of treating disease and the method of treating disease does not require modulating apoptosis.

Groups V and VII are patentably distinct because the method of modulating apoptosis can be used to alter a cell while the method can be used to identify compounds of interest. The protocols and reagents required for modulating apoptosis are materially distinct and separate than those required for identifying compounds of interest. The method of modulating apoptosis do not require the method of identifying compounds of interest and the method identifying compounds of interest does not require the method of modulating apoptosis.

Groups VI and VII are patentably distinct because the method of treatment can be used to treat disease while the method of Group VII can be used to identify compounds of interest. The

protocols and reagents required for treat disease are materially distinct and separate than those required for identifying compounds of interest. The method of treating disease does not require the method of identifying compounds of interest and the method identifying compounds of interest does not require the method of treating disease.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-2982.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 305-0196.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

AU 1633

MICHAEL C. WILSON
PATENT EXAMINER